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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

MAR 30 1992

SUBJECT: Review of Fish Life Cycle Test with Danitol
MRID# 41525901

FROM: Douglas J. Urban, Acting Chief
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Environmental Fate and Effects Division H7507C

Douglas J. Urban 3/30/92

TO: George LaRocca, PM 15
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Registration Division H7505C

The EEB has completed reviewing a fish full life cycle study with Danitol. The study is determined to be invalid but potentially upgradeable with the submission of additional information. If the additional information, identified below, is provided, the study will be re-evaluated.

STUDY TYPE: Fish Life-Cycle Toxicity Test.
Species Tested: Fathead minnow (Pimephales promelas).

CITATION: EPA MRID No. 415259-01

Dionne, E. and D.C. Suprenant. 1990. The chronic toxicity of Fenpropathrin to the fathead minnow (Pimephales promelas). Conducted by Springborn Laboratories, Inc., Wareham, Massachusetts. Laboratory Project No. S-2725. Laboratory Study No. 981.0687.6122.122. Submitted by Chevron Chemical Company, Richmond, California.

Summary of Deficiencies

The test procedures were generally in accordance with protocols recommended by the SEP. However, the following discrepancies were noted:

1. Embryos were reported as being obtained from a brood stock maintained at the testing facility. However, details on how they were obtained were not included in the report.

2. Fish foods (brine shrimp eggs and frozen brine shrimp) were tested for pesticides, but not for metals.

3. Only mean values of biological endpoints and water quality parameters monitored during the test were reported. All raw data must always be submitted with the study report.

4. The flow rate of the diluter system was not reported; therefore, the replacement volumes per day was unknown.

5. The temperature in the test aquaria reached 27°C on 13 separate days during July and August, 1988. On one occasion, the temperature of the exposure solutions was 28-29°C. According to the recommended guidelines, temperature should be maintained at 25°C and should not remain outside the range of 24-26°C for more than 48 hours.

6. The concentration of acetone in the solvent control solution was not reported. However, it was stated in the SLI protocol (Appendix II in the study report) that the concentration of solvent would not exceed 0.1 ml/L.

7. Measured concentrations of Fenpropathrin in all test levels were very inconsistent during the exposure period (Table 3, attached). An example of the fluctuation of measured concentrations is shown in the attached graph (Figure 2) for the highest test concentration. Contrary to the authors' statement, the measured values between replicates were not consistent. The fluctuation might be an indication that the diluting system did not function properly during the test.

8. The control solutions were reported as being collected for chemical analysis. However, the results were not included in the report.

9. The authors stated that "survival data were analyzed first and any treatment levels causing a significant effect on this parameter were excluded from all subsequent analyses of the remaining endpoints (e.g., growth, reproduction)." All treatment levels of each parameter should have been included in their statistical analyses since they were parts of the test and could influence the statistical results.

Required Data

The following information must be provided:

1. Raw growth data (standard length and wet weight),

2. Reproductive data (number of spawns, number of eggs, and number of eggs per female), and

3. Flow rate of diluter system.

Discussion of Other deficiencies

Deficiencies numbered 1, 2, 5, 6, 8, and 9 would not result in the study being judged non-core. No response is required for these problems. Deficiencies 3 and 4 may be eliminated if the additional information is provided.

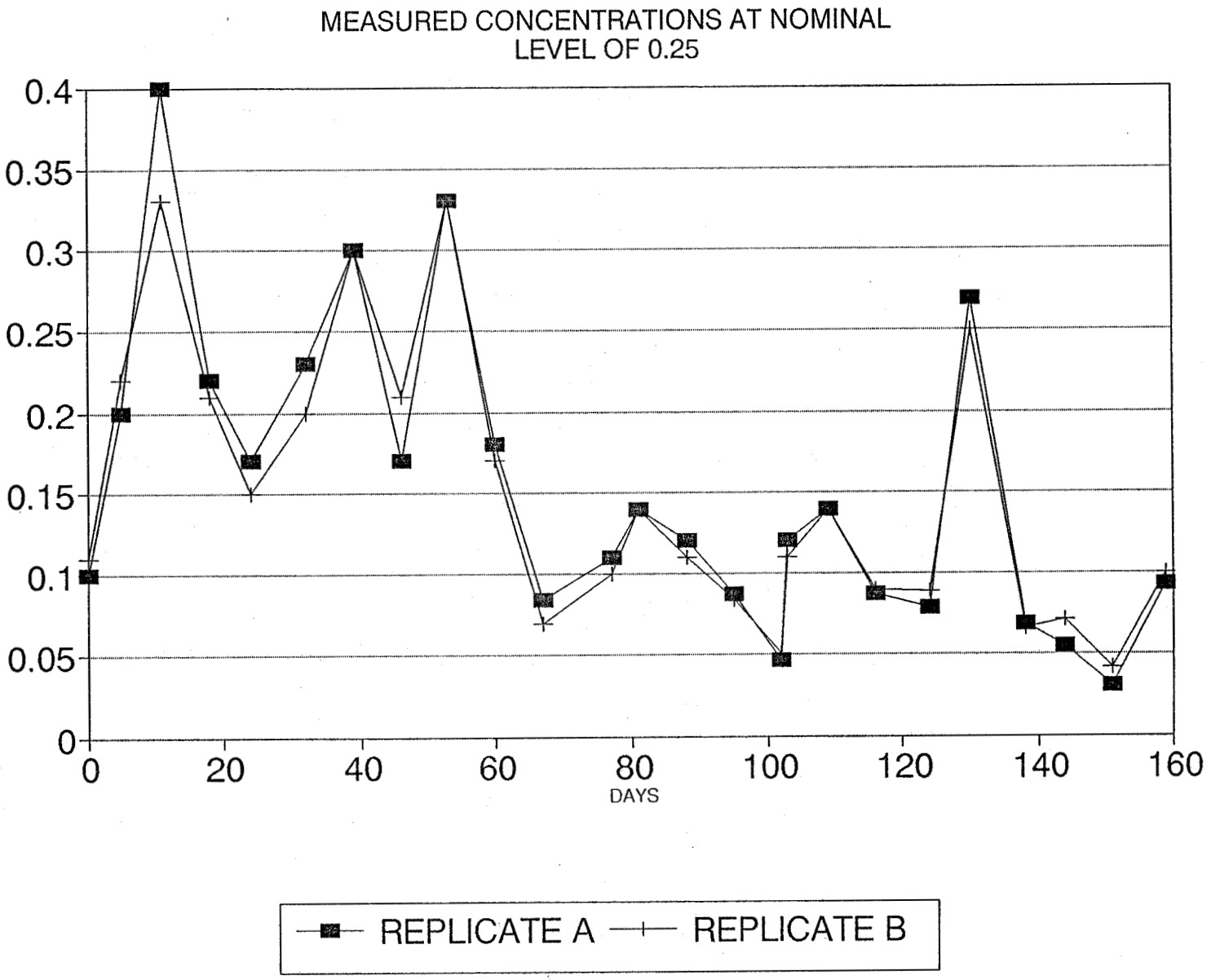
With regard to variation in measured test concentrations, it is possible to reject a study because the measured test concentrations vary significantly from the nominal and/or from each other during the study and between replicates. However, the following two graphs show the measured concentrations at the test level where, according to the information available thus far, no effects were observed and where statistically significant differences were seen compared to the controls. At the nominal concentration of 0.13, the measured concentrations did fluctuate greatly, but they did not seem to drop substantially below 0.05 ppb. Therefore, it may safe to establish a NOEL of 0.05 ppb measured concentration. It is recognized that the measured levels were much higher than this at times, and the average concentration is higher than 0.05 ppb, however, the actual exposure concentrations did settle at 0.05 ppb for an extended period (from about day 70 on). Since the purpose of the study is to determine the sensitivity of the fish throughout its life cycle, the highest concentration we can be sure the fish were exposed to for the entire study is about 0.05 ppb.

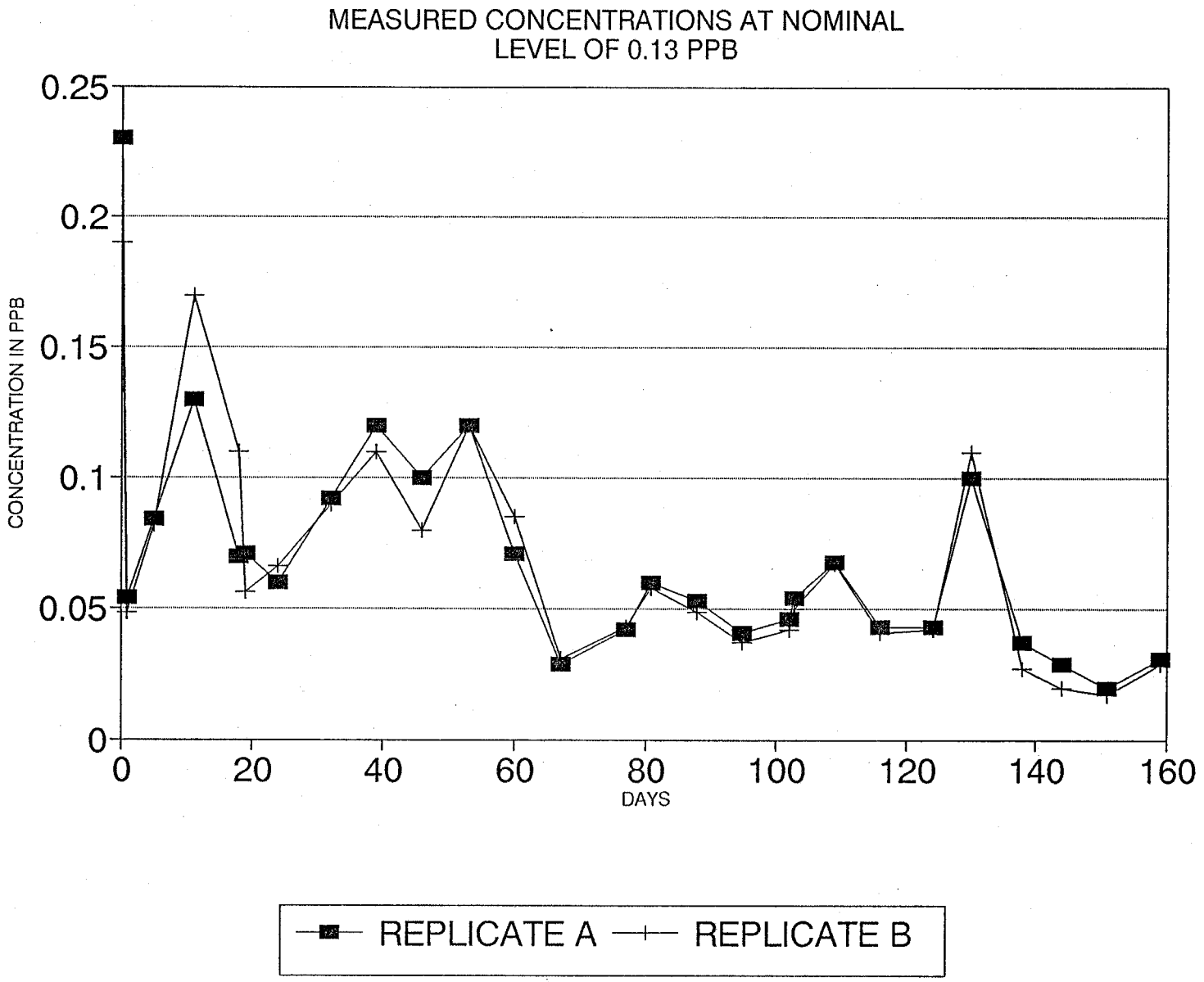
The next higher test level (nominal 0.25) did result in a statistically significant response (total length of Fo fatheads) compared to the control. The graph shows that while the test levels did fluctuate and drop below 0.2 after day 70, during the time when the fish exhibited the reduced growth, the measured concentrations were around 0.2 ppb.

If the additional information is provided and the study can be upgraded to core, it may be possible to derive a NOEL and LOEL from the measured concentrations.

Summary

The above study is invalid but possibly upgradeable. Final conclusion of the NOEL and LOEL will be based on the submitted raw data and flow rate information. If you have questions, please contact Dan Rieder.


MEASURED CONCENTRATIONS AT NOMINAL LEVEL OF 0.25
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
0
20
40
60
80
100
120
140
160
DAYS
REPLICATE A
REPLICATE B


MEASURED CONCENTRATIONS AT NOMINAL LEVEL OF 0.13 PPB
CONCENTRATION IN PPB
0.25
0.2
0.15
0.1
0.05
0
0
20
40
60
80
100
120
140
160
DAYS
REPLICATE A
REPLICATE B